UNIVERSITY OF THE PACIFIC | Thomas J. Long School of Pharmacy

Genentech
A Member of the Roche Group

Fellowship in Industry Program | 2021

Welcome Message from the Associate Dean of Professional Programs

Dear Prospective Fellow,

We are so pleased that you are considering the University of the Pacific's Fellowship in Industry Program (FIP) in partnership with Genentech, Inc. The goal of this program is to increase industry fellowship opportunities offered through partnerships between biopharmaceutical organizations and universities on the West Coast.

At University of the Pacific, the first charter university in California, we value individualized training and focus on leadership development, which are exemplified by our partnership with Genentech. For more than 60 years, the Thomas J. Long School of Pharmacy has been training health care professionals who are problem-solvers, innovators and leaders. Our faculty dives deeper, using research to challenge the status quo of health care and education.

As an FIP fellow, you will be fully immersed in the Clinical Scientist or Clinical Pharmacologist role to support innovative drug development at Genentech. In addition, you will have opportunities to work alongside the faculty and preceptors at the University, Veteran Affairs Palo Alto Health Care System and Travis Air Force Base where you will engage in research collaboration, grant and manuscript development, teaching, student and resident mentoring and other professional development.

I highly encourage you to contact our FIP Director, Dr. Sachin Shah, and the exceptional team of mentors so you can appreciate how deeply committed we are to your future success.

Best Regards,

Allen Shek, PharmD
Professor of Pharmacy Practice
Associate Dean of Professional Programs
University of the Pacific

UNIVERSITY OF THE PACIFIC | Thomas J. Long School of Pharmacy

About University of the Pacific

University of the Pacific is a nationally ranked university with a long tradition of dedicated teaching, small class sizes, practical experience and vibrant residential life. The breathtaking main campus in Stockton, California is home to eight schools and colleges, with more than 80 majors and programs of study. The Thomas J. Long School of Pharmacy opened in 1955 and has a long-standing record for producing high-quality pharmacists with the option for dual degree programs (PharmD/PhD or PharmD/MS) and post-doctoral academic fellowships. Over the last nine years, average annual faculty research grants in the School totaled more than one million dollars with extensive participation in NIH and NSF grants and more than 95 percent of faculty publishing. The School touts a unique decentralized Advanced Pharmacy Practice Experience (APPE) model with seventeen regions having faculty members bolstering teaching, scholarship and service.

Learn more at pharmacy.pacific.edu

Mission

The mission of the Thomas J. Long School of Pharmacy is to prepare students for lifelong success in health careers by providing an excellent, student-centered learning environment. We aspire to develop leadership skills in our students and a strong commitment to their professions, to interprofessional collaboration, and to society. These efforts are assisted by linkages across the University of the Pacific professional and liberal arts programs. We support outstanding professional and graduate teaching, research and other scholarly activity, and services as a means of achieving our mission.

Genentech

A Member of the Roche Group

About Genentech

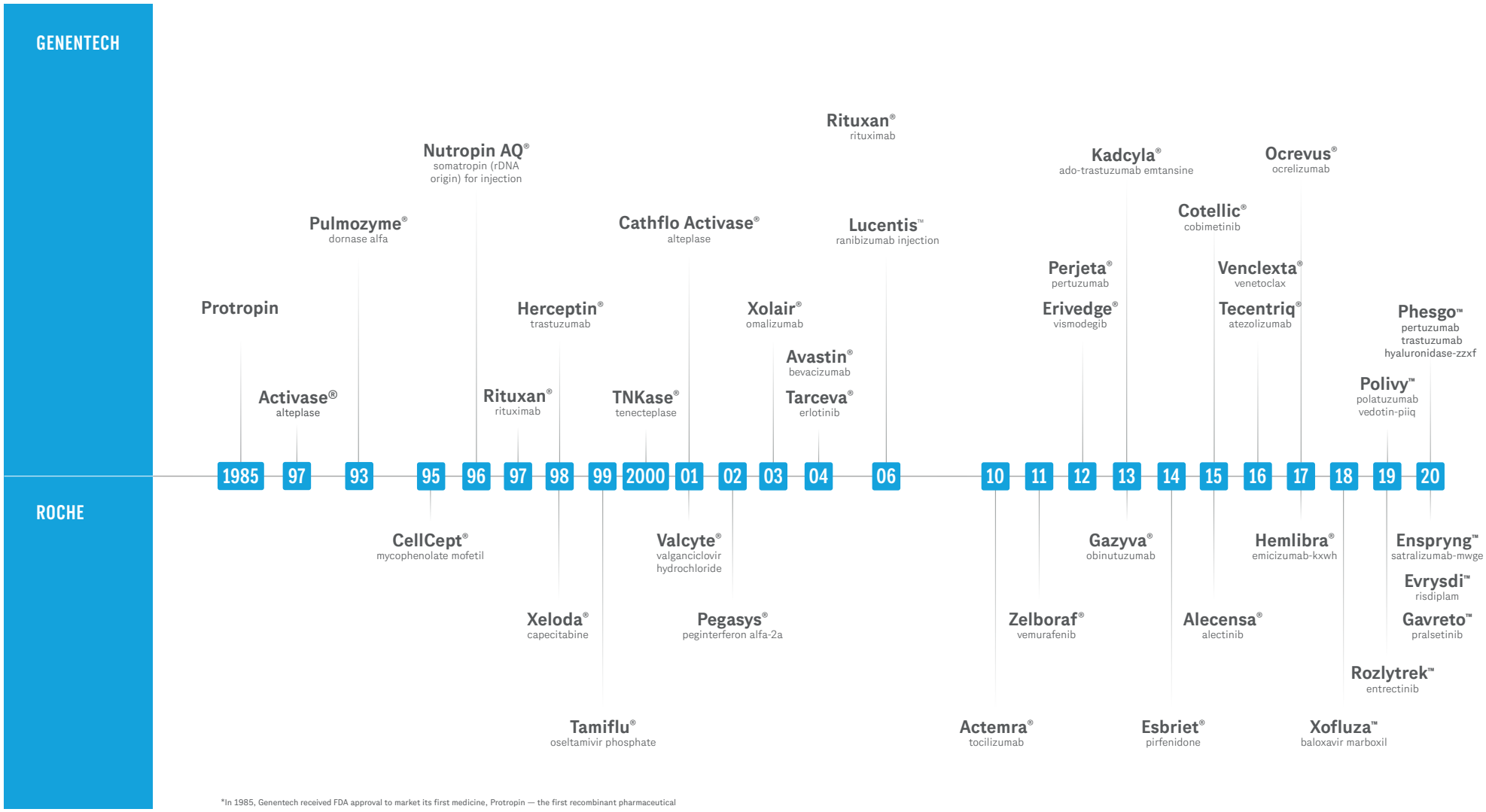
Genentech was founded in 1976, with a goal to develop a new generation of therapeutics created from genetically engineered copies of naturally occurring molecules. Today Genentech continues to use genetic engineering along with other advanced techniques to develop medicines that address major unmet medical needs for patients worldwide.

In March 2009, Genentech became a member of the Roche Group. As part of their merger agreement, Roche and Genentech combined their pharmaceutical operations in the United States. Genentech's South San Francisco campus now serves as the headquarters for Roche pharmaceutical operations in the United States.

The three Roche values — Integrity, Courage, and Passion — are core to how we want to behave, as individuals and collectively as an organization.

- **Integrity** means we are consistently open, honest, ethical and genuine.
- **Courage** means we are entrepreneurial and thus take risks, reach beyond boundaries and experiment.
- **Passion** means we use our drive and commitment to energize, engage and inspire others.

These values define fundamental attributes for guiding decisions and actions leading to increased innovation and business performance.



*In 1985, Genentech received FDA approval to market its first medicine, Protropin — the first recombinant pharmaceutical

Message from Executive Sponsors of Genentech Fellowship

Clinical Science - Ophthalmology, Metabolism, Neurology, Infectious Disease, Immunology – Early Clinical Development

Dear Prospective Fellow,

Genentech is excited to be a part of the University of the Pacific's Fellowship in Industry Program (FIP) for Doctor of Pharmacy graduates. We know that you've worked hard on your career and, as you look forward, we know that you'll continue to be thoughtful regarding your future professional development. Toward that end, we are thrilled to offer you a unique opportunity to grow in an environment that has produced some of the best clinical trialists in the pharmaceutical industry, who in turn have produced some of the most groundbreaking medicines in the world.

As the founder of the biotechnology industry, Genentech, a member of the Roche Group since 2009, has been delivering on the promise of biotechnology for more than 40 years. Our early clinical development group based in South San Francisco offers an incredible range of clinical research training opportunities in immunology, neurology, ophthalmology, infectious diseases and other specialty areas. The early clinical development group here spans Phase 1 and Phase 2 work, and so we are in a unique position to translate discovery research into Phase 3 medicines. We have a culture that supports doing the cutting-edge science that leads to major breakthroughs and cures.

In this environment, we welcome enthusiastic and innovative doctor of pharmacy graduates who strive to transform knowledge into innovative new medicines. Because we recognize the unique backgrounds and skills that each new fellow brings to the program, our group's goal is to give you the support, training and mentorship that will assure your success. We have been part of the fellowship program and are continuing our enthusiastic commitment to developing the next generation of drug developers.

On behalf of Genentech, thank you for considering this program and I invite you to contact us if you have any questions.

Best Regards,

Seppi Lin, MD
Vice President
Head, OMNI Early Clinical Development
Genentech Research and Early Development
Genentech, A Member of the Roche Group

Genentech Fellowship | Clinical Science

This two-year Clinical Science fellowship provides in-depth exposure to Early Clinical Development and understanding the basic principles of clinical research. The fellow will function as a Clinical Scientist and will support Medical Directors/senior-level Clinical Scientists on a diverse set of clinical development activities.

OMNI Early Clinical Development

gRED's OMNI (Ophthalmology, Metabolism, Neurology, Infectious Disease, Immunology) organization is responsible for developing and executing early development clinical strategies in healthy volunteers and patients to provide data for gRED non-oncology new molecular entities with respect to safety, tolerability, efficacy, pharmacokinetics, pharmacodynamics and the utility of biomarkers.

Oncology Early Clinical Development - (Not recruiting this cycle)

Genentech's Oncology Early Clinical Development mission is to provide the clinical leadership and skills to successfully develop novel cancer therapies and the means by which to identify the patients who benefit from them. The organization is responsible for developing strategies for and executing on First-in-Human, Phase 1 and Proof-of-Concept oncology clinical trials. In the role of a Clinical Scientist, the fellow will gain experience in the basic principles of clinical oncology research.

Activities at Genentech

The fellow will function as a clinical scientist and will support medical directors/senior level clinical scientists on the following activities:

- Serve as a clinical science representative on cross-functional sub-teams (i.e. protocol execution, clinical, biomarkers, pharmacokinetics)
- Create, review and present clinical slides for internal (i.e. Genentech/Roche) and external meetings (e.g. Investigator meetings, scientific congresses, advisory boards, site visits, site staff training)
- Develop understanding of Good Clinical Practice (GCP), International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), FDA, EMA, NICE and other relevant guidelines and regulations
- Draft abstracts, posters, manuscripts for scientific meetings
- Author and review of clinical documents (i.e. clinical trial protocols, clarifications and amendments, informed consents, investigator brochures, clinical study reports, investigational new drug submissions)
- Respond to inquiries from health authorities (e.g. FDA, EMA) and study site ethics committees
- Partner with the data management team to assist with the development of case report forms
- Serve as a primary point of contact for study inquiries
- Contribute to ongoing review of the integrity of clinical trial data
- Develop understanding of Phase I-II drug development

Chin Wong, PharmD
Senior Clinical Scientist
Genentech Research and Early Development

Mengsong Li, PharmD
Senior Clinical Scientist
Genentech Research and Early Development

Muaz Sadeia, PharmD
1st Year Clinical Science Fellow
Genentech Research and Early Development

Message from Executive Sponsors of Genentech Fellowship

Clinical Pharmacology

Dear Prospective Fellow,

Genentech's Clinical Pharmacology department is excited to be a part of the University of the Pacific's fellowship program for Doctor of Pharmacy graduates. The comprehensive training of the Doctor of Pharmacy graduate in clinical therapeutics, applied pharmacokinetics, direct patient care, and translational science provides a unique opportunity to develop and contribute as Clinical Pharmacologists in the drug development industry.

Our UOP-Genentech Clinical Pharmacology fellowship program aims to train graduates who have particular interest in Clinical Pharmacology in the areas of pharmacokinetics, pharmacodynamics, drug metabolism, quantitative pharmacology (including various types of PK/PD data modeling and "what-if" simulation approaches), as well as applying new health/IT technologies and advanced analytic approaches to support drug development. We provide the unique opportunity for trainees to work under the supervision of Senior Clinical Pharmacologists and alongside other cross-functional colleagues across Genentech as they complete this 2-year fellowship.

Our Clinical Pharmacology group based in South San Francisco offers an incredible range of training opportunities in many therapeutic areas including Oncology, Immunology, Neurology, Ophthalmology and Infectious Diseases. Our Clinical Pharmacologists are also well known among their scientific peers for their rigorous, innovative and cutting-edge approaches and we encourage them to publish and present at scientific meetings. We pride ourselves for having a culture that focuses on patients, science and our people.

On behalf of Genentech, thank you for considering this program and I invite you to contact us if you have any questions.

Best Regards,

Amita Joshi, PhD
Vice President and Global Head of
Clinical Pharmacology Development Sciences
Genentech Research and Early Development
Genentech, A Member of the Roche Group

Genentech Fellowship | Clinical Pharmacology

The Genentech Clinical Pharmacology Fellowship program builds on the synergy between the fellow's comprehensive Doctor of Pharmacy training and Genentech's innovation in drug development to prepare the individual for a career in the biotechnology/pharmaceutical industry. The fellow will be part of the gRED Clinical Pharmacology Department, which is responsible for applying the principles of quantitative pharmacology to enable selection of a safe and effective dose, route and regimen for small molecules and biologics. The fellow will gain drug development experience at Genentech by completing research projects in clinical pharmacology and/or modeling and simulation and collaborating with scientists across disciplines within Genentech and Roche. These experiences will potentially lead to publications and presentations at scientific conferences and give the fellow exposure to career opportunities in the biotechnology/pharmaceutical industry.

Activities at Genentech

The Fellow will function as a Clinical Pharmacologist and will support research and development projects, which may include the following activities:

- With guidance from the Genentech and University of the Pacific mentors, design and implement a clinical pharmacology and/or modeling and simulation research project(s).
- Present the results of the research project(s) at Genentech, University of the Pacific, a local and/or national scientific meeting and/or publish them in a peer-reviewed journal.
- Serve as a Clinical Pharmacology lead for a healthy volunteer study for a small and/or large molecule project (e.g., food effect, drug-drug interaction, formulation bridging, bioequivalence)
- Serve as a Clinical Pharmacology lead on cross-functional project sub-teams (including clinicians, pharmacologists, biomarker experts, biostatisticians, regulatory experts), facilitating discussions of clinical pharmacology-related issues
- Develop clinical pharmacology plans for small and/or large molecule projects and obtain buy-in from the project team with support from their mentor
- Author clinical pharmacology sections of documents (e.g., clinical trial protocols, investigator brochures, clinical study reports, health authority pre-meeting packages, NDAs, BLAs)
- Develop hands-on modeling and simulation skills (e.g., noncompartmental, compartmental, PK/PD, and population PK modeling)
- Develop an understanding of ICH, FDA, EMA, PMDA and other relevant Clinical Pharmacology guidances and apply them in their work
- Develop an understanding of Phase I-IV drug development in different therapeutic areas

Katie Maass, PhD
Senior Scientist
Genentech Clinical Pharmacology

Elise Oh, PharmD
1st year Clinical Pharmacology Fellow
Genentech Clinical Pharmacology

Activities at the Thomas J. Long School of Pharmacy

The fellow will have clinical faculty status at University of the Pacific, Thomas J. Long School of Pharmacy in Stockton, California.

They will be engaged in:

- Conducting research in collaboration with faculty
- Attending professional development meetings
- Developing grant and manuscript writing skills
- Advising Pacific's Industry Pharmacists Organization (IPhO) student chapter
- Mentoring rotational students in professional development and industry opportunities
- Participating in teaching activities (e.g. industry elective, research elective)

Program Mentors

Allen Shek, PharmD
Professor of Pharmacy Practice
Associate Dean of Professional Programs

Kate M. O'Dell, PharmD, BCPS, FCSHP
Professor of Pharmacy Practice

Nancy N. Nguyen, PharmD, BCPS, AAHIVP, FCSHP
Clinical Professor of Pharmacy Practice
Regional Coordinator – Palo Alto

Sachin A. Shah, PharmD, FACC, FAHA
Professor of Pharmacy Practice
Regional Coordinator – Travis AFB
Director, Fellowship in Industry Program

Activities at Travis Air Force Base

The fellow will have volunteer status at Travis Air Force Base, David Grant USAF Medical Center, Department of Pharmacy.

They will be engaged in:

- Guest lecturing
- Clinical trial support
- IRB and IACUC meetings
- Student and resident mentorship
- Projects relevant to United States Air Force

Program Mentors

Tracey J. McGaughey, PharmD, BCPS
Director of Pharmacy Operations,
Joint Base Andrews, National Capital Region

Vina E. Howarth, Lt Col, USAF, BSC
Chief, Pharmacy Operations
David Grant USAF Medical Center, Travis AFB

Kevin Pham, PharmD
Clinical Research Fellow
Clinical Investigations Facility, Travis AFB

Brief Overview

Fellowship in Industry Program

University of the Pacific's Fellowship in Industry Program (FIP) was founded in 2017 with the goal of providing exceptional biopharmaceutical industry training for PharmD graduates. We strive to deepen domain specific technical skills while sharpening soft skills for all fellows. The fellows will spend 90 percent of their time at Genentech, Genentech Research and Early Development (gRED). The balance of time will be spent on professional development activities with the University.

Unviersity of the Pacific's FIP is unique for several reasons. The program:

1. Integrates pharmaceutical industry training with a blend of academia or hospital practice experiences.
2. Enhances research capabilities via engagement in the Innovative Clinical and Outcomes Research (iCOR) program.
3. Embraces the innovative culture of the San Francisco Bay Area which is home to many health care startup companies.

Sachin A. Shah, PharmD, FACC, FAHA
Professor of Pharmacy Practice
Regional Coordinator – Travis AFB
Director, Fellowship in Industry Program

Jeremy Lim, PharmD
Senior Clinical Scientist
Genentech Research and Early Development
FIP Associate Director and Company Lead

iCOR
innovative clinical & outcomes research

2019-2021 Fellow Clinical Research

Posters and Publications

- Dayal P, **Dimond C**, Yang X, Kent M, Rizzo S, Mohan D. Defining the Frequent Exacerbator Phenotype During a Pandemic in COPD. Abstract at American College of Chest Physicians (CHEST) Annual Meeting 2021; Orlando, FL 2021.
- **Dimond C**, Shah S, Dovan K, Tran B, Hsu K, Pham K, O'Dell K. Effects of Nelumbo nucifera extract on anxiety symptoms in individuals with moderate-to-severe anxiety. [Manuscript in process].
- **Liu X**, **Kawakatsu S**, Tran B, Tran B, Manzenero L, Shih E, Shek A, Lim J, Shah SA. Differences in Glucose Readings Between Right Arm and Left Arm Using a Continuous Glucose Monitor. Poster at American Heart Association-Scientific Sessions, 2020, Virtual Conference. (Abstract #13259). Published as a paper in Journal of Diabetes Science and Technology. https://pubmed.ncbi.nlm.nih.gov/33955249/
- **Kawakatsu S**, Zhu R, Zhang W, Tang MT, Lu T, Quartino A, Kågedal M. Longitudinal Placebo Response Modeling in Patients with Ulcerative Colitis. Poster at American Conference on Pharmacometrics; Aurora, CO, 2020.
- **Kawakatsu S**, Bruno R, Kågedal M, Li C, Girish S, Joshi A, Wu B. Confounding Factors in Exposure-Response Analyses and Mitigation Strategies for Monoclonal Antibodies in Oncology. https://pubmed.ncbi.nlm.nih.gov/33217012/
- **Kim N**, Pham K, Shek A, Lim J, Liu X, Shah SA. Differences in Glucose Level Between Left Arm and Right Arm Using Continuous Glucose Monitors. Poster at American Diabetes Association (ADA) 79th Scientific Sessions; San Francisco, CA 2019.
- Kunder R, Yeh F, Chinn L, Dash A, Lewin-Koh N, **Kim N**, Fredrickson J, Yoshida K, Chen S, Wilson M, and Wong C. Multiple Doses of an Anti-FGFR1/KLB Bispecific Antibody (BFKB8488A) are Associated with a Decrease in Hepatic Fat in Patients with NAFLD. Poster at American Association for the Study of Liver Diseases (AASLD) The Liver Meeting 2019; Boston, MA 2019.
- **Kim N**, Pham K, Shek A, Lim J, **Liu X**, Shah SA. Differences in Glucose Level Between Right Arm and Left Arm Using Continuous Glucose Monitors. Published in Digital Health. https://pubmed.ncbi.nlm.nih.gov/33224517/
- Pham K, **Liu X**, Shah SA, Shek A. Difference in Glucose Levels Between Continuous Glucose Monitor Brands and Application Sites. (Submitted)

On-Going Clinical Research

- Effects of Nelumbo Nucifera Extract on Salivary Cortisol and Anxiolytic Activity in Individuals with Moderate to Severe Anxiety. PI: **Colin Dimond**, PharmD
- Effects of a natural caffeinated energy drink on blood glucose parameters. PI: **Elise Oh**, PharmD.

Perspectives from Fellows

"The Clinical Science fellowship within the OMNI group at Genentech afforded me the opportunity to build and refine the important critical thinking and analytical skills as part of the early clinical development process with support and guidance from incredible mentors. As a Clinical Scientist on the team, I contribute to the clinical trial design and overall clinical development plan through close collaboration with different functions to translate groundbreaking research into late-stage drug candidates to treat diseases in a number of different therapeutic areas. This program's academic affiliation with University of the Pacific is exceptional in its opportunities for close mentorship, innovative clinical research, and unique professional development activities."

Colin Dimond, PharmD
2019-2020 OMNI Clinical Science Fellow

"Through Genentech and UOP, I have been continuously provided with a wide range of activities that have grown my technical and interpersonal skills. The work that I do on a day-to-day basis has lasting and meaningful impact, and my input is valued by my colleagues. I am supported by my mentors every step of the way, and they ensure that my goal of growing as a clinical pharmacologist is met, whether it be in modeling and simulation project or as a clinical pharmacology lead in cross-functional projects. This fellowship has given me all the tools I need to succeed professionally."

Elise Oh, PharmD
2021-2023 Clinical Pharmacology Fellow

Fellowship Eligibility Requirements

A candidate must:

- ❑ Be a permanent resident or citizen of the United States
- ❑ Have earned a PharmD from an ACPE accredited college of pharmacy before the start of the fellowship term

Application Process

Candidates must submit via email (pharmfip@pacific.edu) all the following application materials by the deadline listed on the University website:

- ❑ Letter of intent
- ❑ Updated curriculum vitae (CV)
- ❑ Three (3) letters of recommendation emailed directly from letter writer to FIP director
- ❑ One professional writing sample that demonstrates medical writing ability
- ❑ Unofficial pharmacy school transcript emailed to FIP director
- ❑ All application materials should be addressed to:
  Sachin A. Shah, PharmD, FACC, FAHA
  Director, Fellowship in Industry Program
  Professor of Pharmacy Practice
  Thomas J. Long School of Pharmacy

See application deadline at pacific.edu/pharmacy/fellowship/genentech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